IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

HERBERT FUSSMAN, individually and as ADMINISTRATOR OF THE ESTATE OF RITA FUSSMAN,	)	
Plaintiff,	)	
v.	)	1:06CV149
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

ORDER AND MEMORANDUM OPINION

This matter is before the Court on post-trial motions following a jury trial before this Court on claims by Plaintiff Herbert Fussman, individually and as the Administrator of the Estate of Rita Fussman, ("Plaintiff") against Novartis Pharmaceuticals Corporation ("Defendant" or "Novartis") alleging that Defendant's prescription medications Aredia and Zometa caused Mrs. Fussman to develop Osteonecrosis of the Jaw ("ONJ"), and that Defendant failed to adequately warn Mrs. Fussman and her medical providers, including her oncologist Dr. Heather Shaw, of the risk of ONJ associated with Aredia and Zometa. After a 15-day trial, the jury found in favor of Plaintiff, concluding that Novartis unreasonably failed to provide an adequate warning or instruction with respect to Aredia or Zometa, that the Aredia or Zometa medically caused Mrs. Fussman's jaw injuries, and that Novartis' failure to provide an adequate warning was the proximate cause of Mrs. Fussman's jaw injuries. The jury also found that Novartis breached an implied warranty of merchantability made to Mrs. Fussman regarding Aredia or Zometa. After considering these claims, the jury considered the "learned

intermediary" defense set out in North Carolina General Statute § 99B-5(c), which provides a defense to liability for prescription drug manufacturers for claims based on "failure to warn" if the manufacturer provided an adequate warning to the prescribing physician. However, after considering this defense, the jury found that Novartis did not provide an adequate warning or instruction for Aredia or Zometa to Mrs. Fussman's oncologist, Dr. Heather Shaw, who prescribed the drugs for Mrs. Fussman. The jury also found that the negligence of Novartis proximately caused Mr. Herbert Fussman to lose the consortium of his spouse. Finally, the jury found by clear and convincing evidence that Novartis was liable to the Plaintiff for punitive damages for willful or wanton conduct that Novartis' officers, directors or managers participated in or condoned.

Having reached these conclusions, the jury awarded Plaintiff Herbert Fussman, as the administrator of the Estate of Rita Fussman, $287,000.00 in compensatory damages and $12,600,000.00 in punitive damages on Plaintiff's claims of Negligent Failure to Warn and Breach of the Implied Warranty of Merchantability. However, North Carolina General Statute § 1D-25 provides that "[p]unitive damages awarded against a defendant shall not exceed three times the amount of compensatory damages or two hundred fifty thousand dollars ($250,000), whichever is greater." Therefore, immediately following announcement of the verdict, the Court reduced the punitive damages award pursuant to North Carolina General Statute § 1D-25 to three times the amount of compensatory damages, for a total of $861,000.00 in punitive damages. Based on the jury's verdict, the Court entered Judgment in favor of Plaintiff Herbert Fussman, as the administrator of the Estate of Rita Fussman, on Plaintiff's claims of Negligent

Failure to Warn and Breach of the Implied Warranty of Merchantability, for $287,000.00 in compensatory damages and $861,000.00 in punitive damages, plus prejudgment interest of $110,082.19 on the compensatory damages award. The jury also awarded Plaintiff Herbert Fussman, individually, nominal damages in the amount of $1.00 on his claim for Loss of Consortium, and Judgment was therefore also entered in favor of Plaintiff Herbert Fussman, individually, for $1.00 in nominal damages on his claim of Loss of Consortium, for a total award of $1,258,083.19.

Following entry of the Judgment, Defendant Novartis filed three post-judgment motions that are presently before the Court for review: (1) a Motion for Judgment as a Matter of Law on All Claims [Doc. #539], (2) a Motion for Judgment as a Matter of Law on Punitive Damages [Doc. #535], and (3) a Motion for New Trial [Doc. #537]. For the reasons set forth below, all of these Motions will be denied.[1]

I. Motion for Judgment as a Matter of Law as to All Claims [Doc. #539]

Under Federal Rule of Civil Procedure 50, "[j]udgment as a matter of law is appropriate when there is no legally sufficient evidentiary basis to support the jury's verdict." Private Mortg. Inv. Services, Inc. v. Hotel and Club Assocs., Inc., 296 F.3d 308, 312 (4th Cir. 2002). A motion for judgment as a matter of law should be granted if the jury's findings are not supported by substantial evidence, viewing all the evidence in the light most favorable to the prevailing party

[1] The Court notes that many of the issues raised by Defendant in these Motions were previously raised by Defendant in its Motions for Summary Judgment and Motions in Limine, and the Court finds no basis to reconsider or revisit those prior determinations. The Court will nevertheless address herein the particular contentions raised by Defendant in the present Motions, although the Court will not attempt to repeat here the Court's reasoning to the extent that it has been previously set out in this case.

and drawing all reasonable inferences in favor of the prevailing party. Konkel v. Bob Evans Farms Inc., 165 F.3d 275, 279 (4th Cir. 1999); see also Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 149-50, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000) (noting that in considering a motion under Rule 50, "the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence"); Price v. City of Charlotte, North Carolina, 93 F.3d 1241, 1249 (4th Cir. 1996) ("Because federal courts do not directly review jury verdicts, constrained, as we are, by the Seventh Amendment, the [Defendant] bears a hefty burden in establishing that the evidence is not sufficient to support the awards . . . [and because] we may not substitute our judgment for that of the jury or make credibility determinations, . . . if there is evidence on which a reasonable jury may return verdicts in favor of Appellees, we must affirm." (internal quotations omitted)).

. In the present case, Defendant contends that it is entitled to Judgment as a Matter of Law because Plaintiff failed to present fact and expert testimony to support the failure to warn claims based on either negligence or breach of an implied warranty.[2] Specifically, Defendant contends first that Plaintiff failed to present fact and expert testimony to prove that Novartis was required to give certain warnings, that the warnings if given would have resulted in different medical treatment, and that the different medical treatment would have avoided or mitigated Mrs.

[2] In footnotes in its briefing, Defendant contends that Plaintiff did not prove that Novartis manufactured the Aredia or Zometa received by Mrs. Fussman, and that Plaintiff did not prove when it was sold. However, in Response, Plaintiff notes that there has never been any dispute or question that Novartis was the exclusive manufacturer of Aredia and Zometa, and Plaintiff's medical records support the conclusion that she received Aredia and Zometa, which are manufactured only by Novartis. Therefore, the Court rejects Defendant's contentions as to the implied warranty claim.

Fussman's ONJ. Second, Defendant contends that inconsistencies in the specific causation testimony of Plaintiff's expert, Dr. Najjar, required the jury to speculate as to the cause of Mrs. Fussman's ONJ, and that Dr. Najjar's theory of accelerated bone resorption contradicted Plaintiff's other experts' general causation theory that bisphosphonates such as Aredia and Zometa impede bone resorption. The Court will consider each of these contentions in turn.

With respect first to whether sufficient evidence was presented to support Plaintiff's failure to warn claims, the Court has considered Defendant's contentions and concludes that substantial evidence was presented from which a reasonable jury could have found either for or against Plaintiff on these claims, and the Court will not substitute its view for that of the jury in this case. In that regard, it is clear that the jury found that Novartis unreasonably failed to provide an adequate warning, and substantial evidence was presented to support this conclusion, including expert testimony from both Dr. Marx and Dr. Parisian as to what Novartis knew or should have known regarding the risks of ONJ and the corresponding failure of Novartis to provide an adequate warning of those risks.

There was also sufficient evidence to support the jury's conclusion that the failure to provide an adequate warning was the proximate cause of Mrs. Fussman's injuries. In this regard, Mrs. Fussman's deposition testimony, which was taken before her death in 2009 and which was presented at trial, included her statement that she would not have taken Aredia and Zometa if she knew then what she knows now. In addition, evidence was presented that Mrs. Fussman stopped taking the drug once she was warned of the risks. Moreover, Mrs. Fussman's treating dentists and oral surgeons all testified to various ways they would have changed their treatment

of her had an adequate warning been provided. Finally, the Court notes that although Mrs. Fussman's treating oncologist, Dr. Shaw, testified that she would have recommended that Mrs. Fussman continue on Aredia or Zometa even if there were a risk of ONJ, there was also testimony from which a reasonable jury could have concluded that Dr. Shaw would have changed her treatment of Mrs. Fussman in other ways had she been adequately warned of the risks. In addition, there was testimony from which a reasonable jury could have concluded that at the time of Dr. Shaw's deposition, which was presented at trial, Dr. Shaw still was not fully informed or aware of the risks of ONJ, and on that basis the jury could have chosen to discount Dr. Shaw's statement that she would still have recommended that Mrs. Fussman continue taking Aredia or Zometa. Based on the evidence presented, and viewing it in the light most favorable to Plaintiff, the Court concludes that there was sufficient evidence to support the conclusion that a sufficient warning would have resulted in different medical or dental treatment, and that those differences in treatment would have avoided or mitigated her jaw condition.[3]

With respect to Defendant's contentions regarding Dr. Najjar, the Court finds that there was sufficient testimony presented by Dr. Najjar to support his conclusion, and the jury's

[3] The Court notes that the jury was specifically instructed that in considering whether the alleged failure to provide an adequate warning or instruction with respect to Aredia or Zometa was a proximate cause of Mrs. Fussman's injuries, the jury was required to consider what warning reasonably should have been provided based on what Novartis knew or reasonably should have known at a given time while Mrs. Fussman was taking the drugs, and whether such a warning at that time would have changed the result for Mrs. Fussman. The jury was further instructed that if the jury found that Plaintiff had proved that Novartis should have given a different warning at a particular time, the jury was required to consider whether Plaintiff also proved that the different warning at that time would have resulted in different medical or dental treatment for Mrs. Fussman and that the different treatment would have avoided or mitigated Mrs. Fussman's jaw condition.

finding, that Mrs. Fussman suffered from bisphosphonate-induced ONJ, and that Dr. Najjar had ruled out other conditions, including osteomyelitis, to a reasonable degree of medical certainty. Although there were some potential inconsistencies between Dr. Najjar's testimony and Dr. Marx's underlying causation theory, those inconsistencies were for the jury to consider in according the testimony the weight they believed it deserved. Dr. Marx presented testimony as to general causation, that is, that bisphosphonates such as Aredia and Zometa cause ONJ. Dr. Najjar was not presented to establish general causation, but instead testified as to specific causation based on his differential diagnosis of Mrs. Fussman.[4] In this regard, Dr. Najjar reviewed Mrs. Fussman's medical records, examined her, ruled out other potential causes of her condition, and concluded to a reasonable degree of medical certainty that Mrs. Fussman's ONJ was "because of" bisphosphonates, that is, Aredia and Zometa. Dr. Najjar testified that he specifically considered osteomyelitis but ruled it out because debridement, removal of necrotic bone, and antibiotics would have cured osteomyelitis but did not help Mrs. Fussman. In these circumstances, any inconsistencies or misstatements by Dr. Najjar regarding the underlying mechanism by which bisphosphonates cause ONJ were not critical to the differential diagnosis he provided. In addition, Mrs. Fussman's treating dentists and oral surgeons provided additional

[4] A differential diagnosis "is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated. A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (internal quotation marks and citations omitted).

testimony supporting the conclusion that Mrs. Fussman suffered from bisphosphonate-induced ONJ, not osteomyelitis. Therefore, taking all of the evidence as a whole and taking all reasonable inferences in favor of Plaintiff, the Court concludes that sufficient evidence was presented to support the jury's proximate cause determination in favor of Plaintiff.

Thus, having considered all of the contentions raised by Defendant in its Motion for Judgment as a Matter of Law, the Court concludes that although reasonable minds could differ as to the conclusions to be drawn from the evidence presented, there was sufficient evidence presented to support the jury's verdict in this case. Because the jury's verdict is supported by substantial evidence, the Motion for Judgment as a Matter of Law will be denied.[5]

II. Motion for Judgment as a Matter of Law as to Punitive Damages [Doc. #535]

Defendant has also filed a Motion for Judgment as a Matter of Law as to Damages asking the Court to strike the jury's punitive damage award in this case. In support of this Motion, Novartis contends first that the claim for punitive damages is preempted by the Supremacy Clause of the Constitution because the decision whether to punish Novartis for the labeling and marketing of Aredia and Zometa rests solely with the Food and Drug Administration; and second, that Plaintiff failed to present clear and convincing evidence to support the conclusion that Novartis acted with fraud, malice or willful or wanton conduct that was ratified by Novartis'

[5] The Court notes that Defendant alternatively asserts Rule 59(e) as a basis for its Motion, asking the Court to amend the Judgment in this case and enter Judgment in favor of Defendant. However, Defendant has not stated the basis for asserting a motion under Rule 59(e), nor has Defendant shown any intervening change in controlling law, any new evidence not available at trial, or any clear error of law or manifest injustice. See Ingle v. Yelton, 439 F.3d 191, 197 (4th Cir. 2006) (discussing Rule 59(e) standard). Therefore, to the extent that Defendant has alternatively brought its Motion pursuant to Rule 59(e), that motion would also be denied.

officers, managers or directors.

With respect to Defendant's contention that Plaintiff's claims are preempted by federal law, the Court notes that Defendant presented these same contentions in Defendant's Motion for Summary Judgment as to Punitive Damages. The Court considered those contentions and concluded that Plaintiff's claims were not preempted in light of the Supreme Court's decision in Wyeth v. Levine, 555 U.S. 555, 129 S. Ct. 1187, 1203-04, 173 L. Ed. 2d 51 (2009). The Supreme Court recently reaffirmed its decision in Wyeth as to name-brand, non-generic drugs, noting again that under the applicable federal laws and regulations, a brand-name drug manufacturer is free to strengthen its label in compliance with its state tort duty. See Pliva, Inc. v. Mensing, 131 S. Ct. 2567 (2011). This Court therefore finds no basis to revisit its prior determination in this case with respect to Defendant's preemption contentions. Therefore, Defendant's Motion for Judgment as a Matter of Law on the basis of federal preemption will be denied.[6]

To the extent that Novartis seeks judgment as a matter of law based on an alleged failure

[6] To the extent that Defendant contends that a claim for punitive damages based on "fraud on the FDA" would be preempted, the Court notes that the claim presented in the present case was not based on alleged fraud on the FDA or alleged violation of any federal laws or regulations. Instead, Plaintiff's claim for punitive damages was based on allegations of willful and wanton conduct under state law. As such, the jury was specifically instructed that "this is not a case about FDA enforcement proceedings," it "has not been brought by the FDA for any alleged violation of any FDA regulations," and "it is up to you [the jury] to determine whether Plaintiff has established a claim against the Defendant under state law." Thus, while it is undisputed that "fraud on the FDA" claims are preempted by federal law, the present case does not involve "fraud on the FDA" claims. Instead, the willful and wanton conduct alleged in this case involved intentional deception and suppression of medical evidence by Novartis employees in investigating side effects and communicating with medical professionals, without relying on violation of any FDA rules or regulations. As such, Defendant's "fraud on the FDA" contentions are misplaced.

by Plaintiff to present sufficient evidence to support an award of punitive damages in this case, the Court notes that Defendant raised these contentions as part of its Motion for Summary Judgment on Punitive Damages, which the Court denied. Defendant has essentially renewed its contentions as part of its present Motion for Judgment as a Matter of Law. With respect to a claim for punitive damages under North Carolina law, the claimant bears the burden of showing by clear and convincing evidence that the defendant is liable for compensatory damages, and that "one of the following aggravating factors was present and was related to the injury for which compensatory damages were awarded: (1) Fraud. (2) Malice. (3) Willful or wanton conduct." N.C. Gen. Stat. § 1D-15(a) (2009). Additionally, when the claimant seeks punitive damages against a corporation, the claimant must show that "the officers, directors, or managers of the corporation participated in or condoned the conduct constituting the aggravating factor giving rise to punitive damage." N.C. Gen. Stat. § 1D-15(c). In this case, Plaintiff asserted that Defendant, through its officers, directors, or managers, engaged in willful or wanton conduct, which is "the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage, or other harm. 'Willful or wanton conduct' means more than gross negligence." N.C. Gen. Stat. § 1D-5 (2009). Thus, on Defendant's Motion under Rule 50(b), the Court must consider whether the evidence presented at trial would support a reasonable jury finding by clear and convincing evidence that Plaintiff demonstrated willful or wanton conduct by Novartis' officers, director or managers related to Mrs. Fussman's jaw injuries.

In its Motion for Judgment as a Matter of Law as to Punitive Damages, Defendant

contends that Plaintiff failed to present sufficient evidence to support an award of punitive damages because Novartis "did nothing wrong." Defendant further contends that the evidence presented would not support a finding that Novartis intentionally concealed a risk that it should have known was likely to cause harm, and Defendant also contends that there is no evidence that any alleged "willful and wanton" conduct was related to Mrs. Fussman's jaw injuries. However, based on the evidence presented, the Court concludes that sufficient evidence was presented to support a finding by the jury, by clear and convincing evidence, that Novartis managers intentionally concealed the risk of ONJ and attempted to subvert the medical inquiry regarding the risks of ONJ, all with the knowledge and approval of high-ranking officials within the company. In addition, the evidence would support the conclusion that Novartis managers took this course of action for purely financial reasons, in order to protect its marketing of bisphosphonate drugs. Indeed, the evidence presented at trial against Novartis on this issue was of such sufficient strength that during closing arguments, counsel for Novartis felt compelled to concede that there was "bad news" for Novartis because documents admitted during trial showed that Novartis managers had, in the words of defense counsel, engaged in "improper" thinking, were "less than perfect," and had raised ideas of doing things that "probably should not have been thought about" to prevent publication of or obscure medical evidence regarding risks of ONJ with Aredia and Zometa. In addition, there was sufficient evidence presented to support the jury's conclusion that this intentional deception and suppression of medical evidence by Novartis was related to Mrs. Fussman's jaw injuries, because the evidence was sufficient to support the finding that the actions by Novartis were undertaken as part of an effort to keep

doctors and other medical professionals from learning of the ONJ risks, and it was this lack of adequate warning and information that the jury had already determined was the proximate cause of Mrs. Fussman's injuries.[7]

The Court also notes that Defendant contends that because Mrs. Fussman began to suffer jaw injuries in March 2003, only evidence prior to March 2003 should be considered in making this punitive damages determination. However, the Court at trial rejected this contention and allowed Plaintiff to present evidence of Defendant's continuing conduct during the time period while Mrs. Fussman continued to receive the Aredia and Zometa and her jaw injuries continued. The Court will not reconsider that determination at this time. Therefore, in considering whether sufficient evidence was presented to support the punitive damages award in this case, the Court has considered the evidence presented at trial with regard to Novartis'

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[7] In its brief, Defendant contends that Novartis' conduct could not have been "willful or wanton" unless Novartis intentionally concealed a risk that it should have known was likely to cause harm. From this principle, Defendant apparently takes the position that Novartis cannot be liable even for intentional deception or suppression of the ONJ risks, because the odds of a bisphosphonate user developing ONJ were so small that the deception could not have been "likely" to cause harm. However, the "likelihood" at issue here is not the likelihood of a bisphosphonate user developing ONJ; to adopt Defendant's position on this point would require a plaintiff to establish that the un-warned side effect would appear in over 50% of individuals who used the drug in order to establish that the intentional failure to disclose it was "willful or wanton." Instead, in the present context, the "likelihood" of harm at issue is the likelihood that intentional deception or concealment of medical evidence regarding a potential side effect prevented medical professionals from being adequately warned of the potential side effect, which was then related to the ultimate injury sustained by the Plaintiff. Cf. Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378 (4th Cir. 1995) (upholding punitive damage award for intentional suppression of or deception regarding potential side effects, without requiring that the side effects be "likely" to occur in a majority or certain percentage of individuals using the drug); Everhart v. O'Charley's, Inc., 200 N.C. App. 142, 683 S.E.2d 728 (2009) (concluding that under North Carolina law, punitive damages were available if a plaintiff demonstrated "a connection" between the aggravating conduct and the plaintiff's alleged harm).

conduct during the time period while Mrs. Fussman continued to receive Aredia and Zometa. Having considered this evidence, and for the reasons noted above, the Court concludes that the jury's award of punitive damages is supported by substantial evidence and the Motion for Judgment as a Matter of Law will be denied.[8]

III. Motion for a New Trial [Doc. #537]

In its Motion for a New Trial [Doc. #537], Defendant contends that it is entitled to a new trial under Federal Rule of Civil Procedure 59(a). In considering a motion for a new trial, the Court may weigh the evidence presented during the trial and may consider the credibility of the witnesses in order to determine if the verdict is against the clear weight of the evidence, is based on false evidence, or will result in a miscarriage of justice. See Fed. R. Civ. P. 59(a)(1); Chesapeake Paper Prods. Co. v. Stone & Webster Engineering Corp., 51 F.3d 1229, 1237 (4th Cir. 1995); Poynter v. Ratcliff, 874 F.2d 219, 222-223 (4th Cir. 1989). In addition, a motion for a new trial may "raise questions of law arising out of alleged substantial errors in admission or rejection of evidence." Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 251, 61 S. Ct. 189, 85 L. Ed. 147 (1940). However, Federal Rule of Civil Procedure 61 provides that "[u]nless justice requires otherwise, no error in admitting or excluding evidence – or any other error by the court or a party – is ground for granting a new trial . . . . At every stage of the proceeding,

[8] The Court notes that Defendant alternatively asserts Rule 59(e) as a basis for its Motion, asking the Court to amend the Judgment in this case and remove the punitive damages award. However, Defendant has not stated the basis for asserting a motion under Rule 59(e), nor has Defendant shown any intervening change in controlling law, any new evidence not available at trial, or any clear error of law or manifest injustice. See Ingle v. Yelton, 439 F.3d 191, 197 (4th Cir. 2006) (discussing Rule 59(e) standard). Therefore, to the extent that Defendant has alternatively brought its Motion pursuant to Rule 59(e), that motion would also be denied.

the court must disregard all errors and defects that do not affect any party's substantial rights."

As the basis for the Motion for a New Trial, Defendant contends that (1) Plaintiff failed to present evidence to sufficiently establish that Mrs. Fussman's injury was proximately caused by a lack of warnings; (2) the Court erred in admitting or excluding certain evidence; and (3) the Court erred in instructing the jury with respect to punitive damages and the learned intermediary doctrine. The Court will consider each of these contentions in turn.

1. Motion for New Trial based on Proximate Causation

With respect to Defendant's first contention that there was a lack of evidence of proximate causation, this Court and the Multi-District Court repeatedly rejected this contention prior to trial. In addition, the Court has addressed this issue at length above with respect to Defendant's Motion for Judgment as a Matter of Law, and concluded that sufficient evidence was presented to support the jury's conclusion that the failure to provide an adequate warning was the proximate cause of Mrs. Fussman's injuries. In considering Defendant's present Motion for a New Trial, the Court has considered and weighed the evidence presented at trial and concludes that the jury's proximate cause determination was not against the clear weight of the evidence, was not based on false evidence, and did not result in a miscarriage of justice.

2. Motion for New Trial based on Evidentiary Rulings

With respect to the evidentiary rulings, the Court notes first that most of Defendant's contentions ask this Court to reconsider its prior evidentiary rulings in this case, which the Court is not inclined or persuaded to do here. For example, Novartis contends first that, although the Court initially excluded evidence regarding subsequent changes to the label in 2007, the Court

erred by ultimately allowing some evidence of the 2007 label to be admitted at trial. However, in considering this contention, the Court notes that after the Court agreed to exclude the 2007 label, Defense counsel nevertheless made ongoing references to Novartis' present labels and present FDA approval before the jury. Moreover, Novartis' expert witness, Dr. Arrowsmith, further opened the door to testimony regarding the 2007 label by volunteering information that was then subject to impeachment. Therefore, the Court will not reconsider its determination as to this evidence.

As an additional evidentiary objection, Novartis next argues that the Court improperly excluded the testimony of Dr. McGrath as a "corporate" witness for Novartis. However, the Court repeatedly allowed Defendant the opportunity to present Dr. McGrath's testimony to the extent Defense counsel could provide a sufficient foundation for Dr. McGrath's testimony based on her personal knowledge and not based upon summaries she may have had from other Novartis employees. Defense counsel did not provide this basic level of foundation, even after repeated opportunities and direction from the Court. Defense counsel also declined to call as a witness any other corporate representative with direct knowledge of actions taken by Novartis prior to Dr. McGrath joining Novartis. Thus, the fact that evidence was not presented on this issue is a result of Defense counsel's failure to lay a proper foundation or to present a witness with personal knowledge. Novartis also contends that the Court improperly admitted hearsay in e-mails to Novartis employees from members of Novartis' Advisory Board. However, the statements were not hearsay because they were statements by Novartis or its agents, made on the subject of their work on the Novartis Advisory Board. Moreover, the statements were

introduced to establish what information Novartis employees had received from Novartis' consultants, and the actions Novartis officials took in response, rather than for the truth of the matter asserted. Therefore, the Court will not reconsider its evidentiary determinations on this issue.

Novartis also contends that the Court improperly excluded Dr. Ruggiero's video deposition. However, Novartis did not notice Dr. Ruggiero's deposition for the present case, and was attempting to use a video deposition taken in a separate case, contrary to the rules set out for the Multi-District Litigation. Moreover, the Court during trial noted that Defendant could choose to present Dr. Ruggiero as a live witness. The Court also noted that if portions of the video deposition were presented, Plaintiff would at least be entitled to present the remainder of the video deposition, to which Defendant objected on the basis that the video deposition involved a separate plaintiff's medical information and involved Dr. Ruggiero's expert testimony in that case. The Court finds no basis to reconsider its determination as to Dr. Ruggiero's video deposition.

Novartis also objects to the introduction of evidence showing their national sales figures, which were allowed as part of the punitive damages consideration. However, the Court addressed this issue in rulings prior to and during trial, and the Court finds no basis to reconsider those rulings now. In addition, the jury was instructed that in considering punitive damages, the Plaintiff was required to prove by clear and convincing evidence that any wilful or wanton conduct of Defendant was related to the injury to Mrs. Fussman for which they had already awarded relief, and further that any amount awarded as punitive damages was required

to bear a rational relationship to the sum reasonably needed to punish the Defendant for egregiously wrongful acts committed against Mrs. Fussman. The national sales figure related only to Defendant's ability to pay punitive damages, not to any attempt to impose punitive damages based on potential harm to other individuals.

In sum, as to all of these evidentiary contentions, the Court notes that prior to and during trial in this case, the Court made many evidentiary rulings that were further set out in open court and in the Court's rulings on the parties' Motions in Limine, and Novartis has not presented any basis for reconsideration of those prior decisions. Moreover, even if there were a basis to reconsider those decisions, Novartis has not established that these evidentiary determinations caused substantial harm or would otherwise entitle Novartis to a new trial on the claims.

3. Motion for New Trial based on Jury Instructions

Finally, Novartis contends that the Court erred in failing to give additional jury instructions regarding punitive damages and erred in failing to instruct the jury that Novartis' duty to warn was limited to prescribing physicians. However, the Court gave the jury the North Carolina Pattern instructions for punitive damages and for negligence claims based on a duty to warn. To the extent that Defendant continues to contend that the duty to warn extends, as an initial matter, only to the prescribing physician, the Court considered and rejected that contention in ruling on Defendant's Motion for Summary Judgment prior to trial, and the Court finds no basis to change that determination now.[9] As set out in greater detail in the Court's

[9] Indeed, Defendant's own expert witness, Dr. Arrowsmith, emphasized that warnings regarding Aredia and Zometa in the form of "Dear Health Care Provider" letters were provided not just to prescribing physicians, or even just to doctors, but instead were directed to other health care providers including nurses, dentists, and dental hygienists.

Summary Judgment determination, North Carolina General Statute § 99B-5 provides an affirmative defense in a product liability action - whether based in tort law or contract law - where a prescription drug manufacturer provides an adequate warning to the prescribing physician.[10] This defense was presented to the jury in this case using the language set out in the North Carolina Pattern Jury Instructions, and the jury rejected the defense, concluding in any event that Novartis had failed to provide an adequate warning to Dr. Shaw as Mrs. Fussman's prescribing physician. As such, the Court concludes that there is no basis for Defendant's request for a new trial on this issue.

Thus, having considered all of the contentions raised in the Motion for a New Trial, the Court finally concludes that the jury's verdict was not against the clear weight of the evidence, was not based on false evidence, and will not result in a miscarriage of justice. See Fed. R. Civ. P. 59(a)(1); Chesapeake Paper Prods., 51 F.3d at 1237. The Motion for a New Trial [Doc. #537] will therefore be denied.

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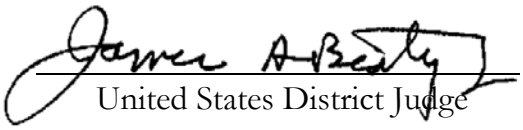
[10] Under the statute, "no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product." N.C. Gen. Stat. § 99B-5(c). Thus, even if a plaintiff otherwise establishes a negligent failure to warn claim, the defendant nevertheless enjoys a "safe harbor" if the defendant can prove that it provided an adequate warning to the prescribing physician. This defense was presented to the jury in this case, and the jury concluded that this defense would not apply because Novartis had not provided an adequate warning to Dr. Shaw as the prescribing physician. This Court finds no basis to provide Defendant with greater protection than that set out in the language of the statute, or to interpret the statute in a way that is contrary to the case law and the North Carolina Pattern Instructions.

IV. CONCLUSION

For the reasons set out above, IT IS ORDERED that Defendant's Motion for Judgment as a Matter of Law on All Claims [Doc. #539], Motion for Judgment as a Matter of Law on Punitive Damages [Doc. #535], and Motion for New Trial [Doc. #537] are DENIED.

This, the 21st day of November, 2011.



United States District Judge